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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,916

Applicant(s)

OTTE, ARIE

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/20/04, 4/5/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-38 and 43-49 is/are pending in the application.
- 4a) Of the above claim(s) 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-38, 43 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of "DNA sequence that is recognized by a heterochromatin-binding protein comprising HP1" in the paper filed 4/5/03 is acknowledged. The traversal is on the ground(s) that the pending claims form a single inventive concept and that all claims are readable on the elected species. This is not found persuasive because of the following reasons. Although most claims are now drawn to the elected species, two claims are not: claims 44-45. Claims 44-45 are drawn to the claimed method using a DNA sequence that binds a fusion protein, such as a fusion protein that binds at lexA or Gal4 DNA binding sites. These fusion proteins are chemically and biologically distinct in structure from heterochromatin-binding protein such as HP1. The DNA sequences recognized by the fusion protein are not drawn to DNA sequences involved in the induction of gene-transcription repressing chromatin, but instead are drawn to generic DNA binding sites, and thus do not share the same corresponding special technical feature because the rest of the assay is simply a prior art assay to measure transcriptional repression. In other words, the special technical feature of the elected invention is drawn to the use of a DNA sequence

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involved in the induction of gene-transcription repressing chromatin in an assay to measure transcription repression, is not the same special technical feature as the use of a DNA sequence recognized by a fusion protein, such as one binding at *lexA* or *Gal4* binding sites, in an assay to measure transcription repression.

The requirement is still deemed proper and is therefore made FINAL.

Claims 44-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 4/5/03.

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 27 attempts to limit the method of claim 26 to the transcription system comprising host cells. However, claim 26

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depends on claim 25 which recites use of host cells and thus the claim does not further limit the parent claim.

Claim 37 is objected to because of the following informalities: the abbreviation of fluorescence-activated cell sorter is indicated as "FAGS". This is an incorrect abbreviation (the "G" should be a "C") which is also a term that is considered to be offensive. Because the abbreviation is not further used in the claims, it should be deleted. Appropriate correction is required.

Claim 43 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 43 is drawn to limiting the method of claim 25 to DNA sequences that is selectively recognized by at least one DNA-binding protein and the organism also expresses a protein complex comprising a first part selectively binding the DNA sequence and a second part inducing the formation of chromatin in which the transcription is repressed. These limitations do not further limit the method of claim 25 because the DNA sequence that is recognized by a heterochromatin-binding protein comprising HP1 is selectively recognized by a DNA-binding

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protein and the (host cells/transcription system) must express the protein complex having the claimed properties for the method to function.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-38, 43, and 46-49 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of detecting a DNA sequence comprising the use of a DNA sequence involved in the induction of gene-transcription repressing chromatin, which DNA sequence is recognized by a heterochromatin-binding protein comprising HP1. In the absence of any structural information concerning the DNA sequence used in the claimed method, it is

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assumed that the DNA sequence as claimed constitutes a genus of compounds defined only by their function: recognized by a heterochromatin-binding protein comprising HP1. Thus, the claims are drawn to a genus of the use of compounds that is defined only by their function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims and the specification is drawn to the function of the DNA sequence used in the claimed method: recognized by a heterochromatin-binding protein comprising HP1. The application as filed does not describe even one sequence that meets the functional limitation, let alone the structure of the genus of DNA sequences recognized by HP1. There is no evidence that the function of the DNA sequence provides a detailed chemical description of the structure of the DNA sequence that has that function because in the DNA art, in the absence of any specialized information, function does not

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usually provide a description of the structure of DNA that has that function. Accordingly, in the absence of sufficient recitation of distinguishing structural characteristics, the specification does not provide adequate written description of the claimed genus of methods using the DNA sequence.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of DNA sequences that are recognized by a heterochromatin-binding protein comprising HP1, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is

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required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claims fail to meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-38, 43, and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, etc, the use of "cloning in a vector of DNA fragments between ..." renders the claims vague and

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indefinite because grammatically the phrase makes no sense (is there a vector of DNA fragments used in the claim, and if there is, what is cloned in?) Amending the claims to recite what is intended in a grammatically correct and clear form would be remedial. It was assumed that the applicant intended that the DNA fragments were cloned into vectors at a location between i) and ii).

Regarding claim 25, etc, there is no clear positive antecedent basis for "the host cells" of step 3). Also, "the DNA sequence" referred to in step 3) lacks positive antecedent basis (and thus should be indicated by "a" instead of "the").

Regarding claim 25, the use of "which HP1-comprising complex" renders the claims vague and indefinite because the antecedent is "protein" not "complex".

Regarding claim 37, there is no clear positive antecedent basis for "the fluorescent host cells".

Regarding claims 43 and 46, etc, there is no positive antecedent basis for "the organism".

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such

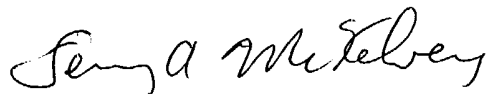
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papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

April 5, 2004